

## **REMARKS**

### **I. Status of the Application**

Claims 1-3 and 7-39 are presently pending in the application. Claims 8-26 and 36 have been withdrawn by the Examiner. Claims 1 and 29 have been amended to recite a non-crosslinked polymer, support for which is found at page 15 line 17 of the specification.

Claims 1-3, 7, 27, 28, 33-35, and 37 stand rejected under 35 U.S.C. § 103(a) as being obvious over Amsden US 2003/0105245 in view of Grieshaber US 2002/0013546. Claim 29 stands rejected under 35 U.S.C. § 103(a) as being obvious over Noda US 6,669,711 in view of Amsden. Claim 30 stands rejected under 35 U.S.C. § 103(a) as being obvious over Amsden US 2003/0105245 in view of Grieshaber US 2002/0013546 and further in view of Noda US 6,669,711. Claims 37-38 stand rejected under 35 U.S.C. § 103(a) as being obvious over Amsden US 2003/0105245 in view of Grieshaber US 2002/0013546 and further in view of Bays US 4,650,488. Claim 39 stands rejected under 35 U.S.C. § 103(a) as being obvious over Amsden US 2003/0105245 in view of Grieshaber US 2002/0013546 and Bays US 4,650,488 and further in view Martin US 5,017,188.

Applicants respectfully request reconsideration of the foregoing claims in view of the amendments and remarks.

### **II. Claims 1-7, 27, 28, 33-35 and 37 Are Not Obvious Over Amsden and Grieshaber**

At page 6 of the present office action, claims 1-7, 27, 28, 33-35, and 37 stand rejected under 35 U.S.C. § 103(a) as being obvious over Amsden US 2003/0105245 in view of Grieshaber US 2002/0013546. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

Claim 1 has been amended to recite a non-crosslinked polymer so as to distinguish the claimed polymer from crosslinked polymers. The specification teaches at page 15, line 17 that the polymer “should not contain chemical cross-links.”

Amsden, which is directed to thermally crosslinked and photo-crosslinked polymers, fails to teach or suggest drains having non-crosslinked polymers as claimed. Grieshaber, relied upon for the teaching of a drain, fails to cure the deficiencies of Amsden.

Amsden is very clearly directed to the formation of a crosslinked polymer. For example, at page 1 paragraphs 6, 7, and 8, the invention of Amsden is summarized as follows:

In accordance with one aspect of the invention there is provided a method of preparing a thermally crosslinked biodegradable/biocompatible elastomeric polymer comprising: combining a star co-polymer with a bislactone crosslinking agent, and heating the combined star co-polymer and crosslinking agent, so that a crosslinked biodegradable/biocompatible elastomeric polymer is prepared.

In accordance with another aspect of the invention there is provided a method of preparing a photo-crosslinked biodegradable/biocompatible elastomeric polymer comprising: combining a photo-crosslinkable star co-polymer with an initiator, and exposing the combined photo-crosslinkable star copolymer and initiator to photo-crosslinking light, so that a crosslinked biodegradable/biocompatible elastomeric polymer is prepared.

The invention further provides a thermally crosslinked biodegradable/biocompatible elastomeric polymer, and a photo-crosslinked biodegradable/biocompatible elastomeric polymer.

Amsden provides no teaching of a non-crosslinked polymer or a thermoplastic polymer as applicants have previously argued and Amsden only teaches polymers that are thermally crosslinked or photo-crosslinked. In addition, the Examiner acknowledges that Amsden fails to teach or suggest a drain, and especially a drain formed from a thermoplastic non-crosslinked polymer as claimed.

Further, Amsden fails to teach a polymer with an elastic modulus of less than 120MPa. The Examiner believes that Grieshaber teaches a tube, but there is no teaching that the tube is formed from a polymer having an elastic modulus of less than 120MPa.

In addition, the tube of Grieshaber is not biodegradable, but is intended to be permanently left inside an individual as a structural support element. The biodegradable drain of the pending application is intended to be left inside the body for an extended period of time, specifically to “remain functional in the body or antrum orifice for the duration of the prescribed, clinical appropriate period of time to accomplish the predetermined therapeutic purpose.” See page 5, lines 7-9 of the pending application. In fact, the drains are intended to maintain their functional properties for 2 to 12 weeks or in some situations for several months. See page 16, lines 13-15 and page 17, lines 22-24. This is not true with the tube of Grieshaber.

Since the Examiner’s combination of Amsden and Grieshaber fails to teach all of the claim limitations of the amended claims now presented, the combination of Amsden and Grieshaber does not create a prima facie case of obviousness.

In addition, applicants respectfully submit that the cited art provides no motivation to modify the polymer of Amsden for use as a biomedical device from being crosslinked to being non-crosslinked. Amsden discusses the disadvantages due to the nature of prior art crosslinked polymers. The goal of Amsden is to provide a medical device fashioned from a crosslinked polymer which avoids the disadvantages of the prior art.

### **III. Claim 29 is Not Obvious Over Noda and Amsden**

At page 6 of the office action, claim 29 stands rejected under 35 U.S.C. § 103(a) as being obvious over Noda US 6,669,711 in view of Amsden. Applicants respectfully traverse the

rejection as to the amended claims now presented. The Examiner admits that Noda fails to teach the claimed polymer. As detailed above, Amsden fails to teach the claimed drain including a non-crosslinked polymer. Since the Examiner's combination of Noda and Amsden fails to teach all of the claim limitations of the amended claims now presented, the combination of Noda and Amsden does not create a prima facie case of obviousness.

**IV. Claim 30 Is Not Obvious Over Amsden, Grieshaber and Noda**

At page 8 of the present office action, claim 30 stands rejected under 35 U.S.C. § 103(a) as being obvious over Amsden, Grieshaber and Noda US 6,669,711. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

For the reasons discussed above, the combination of Amsden and Grieshaber fails to teach or suggest all of the limitations of claims 29 and 30. Noda, which is relied upon for the teaching of a nasal drain, fails to cure the deficiencies of Amsden and Grieshaber. Further, one of skill in the art of biodegradable drains would not look to Noda because Noda discloses a surgical balloon that "prevents a liquid or gas from flowing from one area of the body to another area." See col. 2, lines 49-52. This is the opposite desired effect of the disclosed drain. Accordingly, applicants respectfully request that the rejection of claims 29 and 30 based on Amsden, Grieshaber and Noda be withdrawn.

**V. Claims 37 and 38 Are Not Obvious Over Amsden, Grieshaber and Bays**

At page 9 of the present office action, claims 37 and 38 stand rejected under 35 U.S.C. § 103(a) as being obvious over Amsden, Grieshaber and Bays US 4,650,488. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

For the reasons discussed above, the combination of Amsden and Grieshaber fails to teach or suggest all of the limitations of claims 37 and 38. Bays fails to cure the deficiencies of Amsden and Grieshaber. Accordingly, applicants respectfully request that the rejection of claims 37 and 38 based on Amsden, Grieshaber and Bays be withdrawn.

**VI. Claim 39 Is Not Obvious Over Amsden, Grieshaber, Bays and Marten**

At page 9 of the present office action, claim 39 stands rejected under 35 U.S.C. § 103(a) as being obvious over Amsden, Grieshaber, Bays and Marten US 5,017,188. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

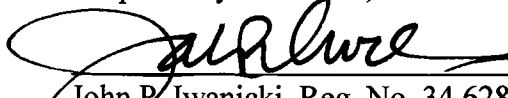
For the reasons discussed above, the combination of Amsden, Grieshaber and Bays fails to teach or suggest all of the limitations of claim 39. Marten fails to cure the deficiencies of Amsden, Grieshaber and Bays. Accordingly, applicants respectfully request that the rejection of claim 39 based on Amsden, Grieshaber, Bays and Marten be withdrawn.

**VII. Conclusion**

Having addressed all outstanding issues, applicants respectfully request reconsideration and allowance of this case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below. The Commissioner is authorized to apply any additional charges or credits to Deposit Account No. 19-0733.

Dated: March 28, 2011

Respectfully submitted,

  
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